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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/580,252	05/22/2006	Hiromi Kataoka	028567-0146	2043
22428 7590 04/14/2009 FOLEY AND LARDNER LLP SUITE 500 3000 K STREET NW WASHINGTON, DC 20007				
EXAMINER				
CHAWAN, SHEELA C				
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2624				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/580,252

Applicant(s)

KATAOKA, HIROMI

Examiner

SHEELA C. CHAWAN

Art Unit

2624

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 May 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 10-18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 15 and 18 is/are allowed.
- 6) ☒ Claim(s) 10-14, 16 and 17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 22 May 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/06)
Paper No(s)/Mail Date 5/22/06, 8/22/06
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Priority

1. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Preliminary Amendment

2. Preliminary amendment filed on 5/22/06 has been entered.

Claims 1-9 are canceled,

Claims 10-18 are pending in the application.

Information Disclosure Statement

3. The information disclosure statement (IDS) submitted on 5/22/06, 8/22/06, the information disclosure statement is being considered by the examiner.

Drawings

4. The Examiner has approved drawings filed on 5/22/06.

Claim Rejections - 35 USC § 101

5. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 13 and 16 are rejected under 35 U.S.C. 101 as not falling within one of the four statutory categories of invention. The Federal Circuit¹, relying upon Supreme

¹ *In re Bilski*, 88 USPQ2d 1385 (Fed. Cir. 2008).

Court precedent², has indicated that a statutory "process" under 35 U.S.C. 101 must (1) be tied to a particular machine or apparatus, or (2) transform a particular article to a different state or thing. This is referred to as the "machine or transformation test", whereby the recitation of a particular machine or transformation of an article must impose meaningful limits on the claim's scope to impart patent-eligibility (See *Benson*, 409 U.S. at 71-72), and the involvement of the machine or transformation in the claimed process must not merely be insignificant extra-solution activity (See *Flook*, 437 U.S. at 590"). While the instant claim(s) recite a series of steps or acts to be performed, the claim(s) neither transform an article nor positively tie to a particular machine that accomplishes the claimed method steps, and therefore do not qualify as a statutory process.

Claim Rejections - 35 USC § 101

6. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 14 and 17 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter as follows. Claim 14 and 17 defines "A computer – readable recording medium". The terminology "A computer – readable recording medium" alone has no set definition. "The examiner suggests amending the claim to embody the program on "computer-readable medium encoded with a computer program" for performing the steps of or equivalent in order to make the claim statutory.

² *Diamond v. Diehr*, 450 U.S. 175, 184 (1981); *Parker v. Flook*, 437 U.S. 584, 588 n.9 (1978); *Gottschalk v. Benson*, 409 U.S. 63, 70 (1972); *Cochrane v. Deener*, 94 U.S. 780, 787-88 (1876).

Any amendment to the claim should be commensurate with its corresponding disclosure.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 10-14, are rejected under 35 U.S.C. 102(a) as being anticipated over Hiromi Kataoka et al., "Clustering and 3D visualization of Leukocyte scattergrams", "Medical information", Vol. 22, 2002, pages 209-210.

As to claim 10, Kataoka discloses a similar-pattern searching apparatus for searching a pattern having a high similarity to a target pattern of a test sample from a group of patterns including a plurality of patterns, the similar-pattern searching apparatus comprising (Abstract):

a storage unit that stores therein a class map generated by selecting a model parameter that characterizes a plurality of component fractions included in each pattern in the group and by clustering the patterns based on selected model parameter (Abstract); and

a similar-pattern searching unit that selects a class similar to a component fraction included in the target pattern from the class map in the storage unit (abstract).

As to claim 11, Kataoka discloses the similar-pattern searching apparatus according to claim 10, wherein the patterns are any one of one-dimensional and multi-dimensional (abstract).

As to claim 12, Kataoka discloses the similar-pattern searching apparatus according to claim 11, wherein the patterns are any one of leukocyte particle size patterns, protein electrophoretic waveforms, and blood cell histograms (abstract).

Regarding claim 13, it is interpreted and thus rejected for the same reasons as applied above in the rejection of claim 1.

Regarding claim 14, it is interpreted and thus rejected for the same reasons as applied above in the rejection of claim 1.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 10 -11, 13 and 15, are rejected under 35 U.S.C. 102(b) as being anticipated by Tom Heskes, "self –organizing maps, vector quantization, and mixture modeling", IEEE Transactions on neural networks, Vol. XX, No. Y, pp.1-7 (2001).

As to claim 10, Heskes, disclose a similar-pattern searching apparatus for searching a pattern having a high similarity to a target pattern of a test sample from a

group of patterns including a plurality of patterns, the similar-pattern searching apparatus comprising (Abstract):

a storage unit that stores therein a class map generated by selecting a model parameter that characterize a plurality of component fractions included in each pattern in the group and by clustering the patterns based on selected model parameter (Abstract, section II, self – organizing maps and vector quantization, section III, EM algorithm without missing values, section IV, a mixture- modeling interpretation, section V EM algorithm with missing values, section VI. Other probability models); and

a similar-pattern searching unit that selects a class similar to a component fraction included in the target pattern from the class map in the storage unit (abstract, section II , self – organizing maps and vector quantization, section III, EM algorithm without missing values , section IV, a mixture- modeling interpretation, section V EM algorithm with missing values, section VI. Other probability models).

As to claim 11, Heskes discloses the similar-pattern searching apparatus according to claim 10, wherein the patterns are any one of one-dimensional and multi-dimensional (abstract).

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Tom Heskes, "self –organizing maps, vector quantization, and mixture modeling", IEEE Transactions on neural networks, Vol. XX , No. Y, pp.1-7 (2001), as applied to claims 10-11, 13 and 14, above and further in view of Nishikiori et al., (US. 6,246,786 B1).

Tom Heskes disclose self –organizing maps are popular tools for clustering and visualization of high-dimensional data through vector quantization, and mixture modeling. Heskes is silent about patterns are any one of leukocyte particle size patterns, protein electrophoretic waveforms, and blood cell histograms.

Nishikiori discloses a particle analyzer for measuring the number and characteristics of particles to be analyzed, for example blood cells in a liquid sample and judging the characteristics of particles from the scattergram. The system comprises of: wherein the patterns are any one of leukocyte particle size patterns, protein electrophoretic waveforms, and blood cell histograms (column 6, lines 18- 47, column 7, lines 14- 36).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to have modified Heskes to include wherein the patterns are any one of leukocyte particle size patterns, protein electrophoretic waveforms, and blood cell histograms. It would have been obvious to one of ordinary skill in the art at the time of the invention to have modified Heskes by the teaching of Nishikiori in order to provide a particle analyzer to enable a user to judge a distribution state easily and immediately at the sight of a displayed distribution diagram (as suggested by Nishikiori at column 1, lines 35- 38).

Allowable Subject Matter

10. The following is a statement of reasons for the indication of allowable subject matter:

Claims 15 and 18 are allowed.

The closest prior art to Hiromi Kataoka et al., and Nishikiori et al., (US. 6,246,786 B1) fails to teach or suggest, at least a primary clustering unit that clusters the leukocyte particle size patterns, which are obtained by measurement, in the group while applying a self-organizing map to the leukocyte particle size patterns to thereby generate a primary class map; a first-parameter determining unit that executes an EM algorithm for each leukocyte particle size pattern included in the primary class map by using predetermined initial values to thereby determine first-mixture-distribution model parameters including number of cellular components contained in each leukocyte particle size pattern and an average, a variance, and a density of each cellular component; a second-parameter determining unit that executes an EM algorithm for each leukocyte particle size pattern in the group by using the first-mixture-distribution model parameters as initial values to thereby determine second mixture distribution model parameters including number of the cellular components contained in each leukocyte particle size pattern, and an average, a variance, and a density of each cellular component; a secondary clustering unit that clusters the leukocyte particle size patterns in the group while applying the self-organizing map to the first mixture distribution model parameters to thereby generate a secondary class map; an inter-class distance master generator that calculates similarity distances between all

combinations of the classes included in the secondary class map, and that generates an inter- class distance master that includes a correspondence of each combination of the classes and the similarity distance for the combination; a storage unit that stores therein the secondary class map and the inter-class distance master; a class determining unit that determines a target class belonging to each of cellular component fractions included in the target leukocyte particle size pattern from the secondary class map in the storage unit; and a similar-pattern searching unit that detects, as a similar class, a class from the inter- class distance master for which similarity distance from the target class is equal to or smaller than a predetermined threshold, and that determines a leukocyte particle size pattern included in the similar class as a pattern having a high similarity to the target leukocyte particle size pattern as recited in claim 15.

Futhermore, the closest prior art to Hiromi Kataoka et al., and Nishikiori et al., (US. 6,246,786 B1) fails to teach or suggest, at least a fraction separating apparatus for separating a plurality of cellular component fractions included in a leukocyte particle size pattern, the fraction separating apparatus comprising: a primary clustering unit that clusters a plurality of leukocyte particle size patterns, which are obtained by measurement, while applying a self-organizing map to the leukocyte particle size patterns to thereby generate a primary class map; a parameter determining unit that executes an EM algorithm for each leukocyte particle size patterns included in the primary class map by using predetermined initial values to thereby determine mixture distribution model parameters including number of cellular components contained in each leukocyte particle size pattern, and an average, a variance, and a density of each

cellular component fractions; and a fraction separating unit that executes an EM algorithm for each leukocyte particle size pattern by using the mixture distribution model parameters as initial values to thereby separate the cellular component fractions included in each leukocyte particle size pattern as recited in claim 18.

Other prior art cited

11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Matsuda et al., (US. 4,617,275) discloses reagent for blood analysis.

Matsuda et al., (US. 4,656,139) discloses method for preparing cells for blood analysis.

Contact Information

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheela C Chawan whose telephone number is. 571-272-7446. The examiner can normally be reached on Monday - Friday 8.30 am - 5.00 pm and every Wednesday works from home. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Vikram Bali can be reached on 571-272-7415. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Sheela C Chawan/

4/10/09

Primary Examiner, Art Unit 2624

